DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Teratech Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

May 9, 2015

Re: K150533
Trade/Device Name: Terason uSmart3200T Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 22, 2015
Received: April 23, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Terason uSmart3200T Ultrasound System, as described in your premarket notification:

Transducer Model Number

9MC3	8TE3	PDOF	15L4	12L5A
8L2	8V3A	16HL7	8EC4A	5C2A
4V2A				

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See P R A Statement on last page.

510(k) Number *(if known)*
K150533

Device Name
Terason uSmart3200T Ultrasound System

Indications for Use *(Describe)*

The Teratech Corporation Terason™ uSmart3200T is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Ophthalmic, Fetal, Abdominal, Intra-operative (Spec. and Neuro.), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal (non-cardiac), Musculo-skeletal (Conventional and Superficial), Cardiac (Adult & Pediatric), Trans-esophageal (cardiac), and Peripheral Vascular.

Type of Use (*Select one or both, as applicable*)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over The Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (C D R H) (*Signature*)

P S C Publishing Services (301) 443-6740 EF

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T Ultrasound System

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic	N	N	N		N	N	N
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Trans-rectal[f]:	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Trans-vaginal[g]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N	N	N	N	N
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P[1]: uses previously cleared under K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 9MC3 Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	N	N	N		N	N	N
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[d]:	N	N	N		N	N	N
	Adult Cephalic[d]:	N	N	N		N	N	N
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N		N	N	N	N
	Cardiac Pediatric	N	N		N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	N	N	N	N	N	N	N
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 8TE3 Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N	N	N	N	N
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – PDOF Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 15L4 Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic	N	N	N		N	N	N
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 12L5A Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic	N	N	N		N	N	N
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 8L2 Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 8V3A Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K140773

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 16HL7 Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K110020

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 8EC4A Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-vaginal[g]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K112953

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T – 5C2A Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Abdominal[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Musculo-skel. (Superfic)[d]:	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Cardiac Pediatric	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K112953
P[2]: uses previously cleared under K131209

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T - 4V2A Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Abdominal[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Adult Cephalic[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Cardiac Pediatric	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K112953
P[2]: uses previously cleared under K131209

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) Summary or Statement

Teratech Corporation

Terason uSmart3200T Ultrasound System

1. **Sponsor:**

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Ben Chiampa
Director of Quality Assurance
Telephone: 781-270-4143

Date Prepared: March 31, 2015

2. **Device Name**

Proprietary Name: Terason uSmart3200T Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

Ultrasonic Pulsed Doppler Imaging System
(21 CFR 892.1550, 90-IYN)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. **Predicate Device**

Terason uSmart3200T Ultrasound System (K140524)

Supporting Predicate Devices:
Terason™ T3000 8MC3 Transducer (K112953)
Philips (Oldelft) S7-3t TE Transducer Probe (K132304)
Aloka/Terason Ultrasound System with PDOF Transducer (K110482)
Terason uSmart3300 8L2 and 8V3A Transducers (K140773)
Sonosite Edge System L25x/13-6 Transducer (K082098)

4. Intended Use

The Teratech Corporation Terason™ uSmart3200T is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Ophthalmic, Fetal, Abdominal, Intra-operative (Spec. and Neuro.), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal (non-Cardiac), Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Trans-esophageal (Cardiac) Peripheral Vascular.

5. Device Description

The Terason uSmart3200T ultrasound system is a portable tablet-style, full-feature, general purpose diagnostic ultrasound system used to acquire and display high–resolution, real-time ultrasound data through multiple imaging modes. The Terason uSmart3200T Ultrasound System is equivalent to the previously cleared versions of the uSmart3200T Ultrasound Systems. The modification includes the addition of 5 transducers (9MC3, 8TE3, PDOF, 8L2, 8V3A), the Trans-esophageal (non-Cardiac and Cardiac) IFUs and the Ophthalmic IFU associated with the 12L5A and 15L4 transducers with no change to the tablet-style computer form factor.

The Terason™ uSmart3200T ultrasound system was the previously cleared on the dates of May 28, 2013 and May 21, 2014 as described in the 510(k) submission (K140524). This system contains a proprietary ultrasound engine for controlling the acoustic output of the transducer and processing the return echoes in real time. These data are then transferred to the tablet computer over a FireWire (aka IEEE 1394) connection for further processing and generation/display of the ultrasound image.

The Terason™ uSmart3200T ultrasound tablet weighs 4.9 pounds (2.21 Kg) and has an 11.5” backlit touch screen. The tablet dimensions (8.82”(H) x 12.64”(W) x 1.25”(D)) are chosen to allow portability. A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning. The tablet includes a docking station (for charging) that uses a medical-grade power supply. The ultrasound transducer connector is identical to that used in the Terason™ predicate devices, the uSmart3200T and uSmart3300. Optional accessories include a cart and printer.

6. Technology Characteristics

The design and construction of the Terason uSmart3200T is the same as the Terason uSmart3200T Ultrasound system which was cleared in May 2013 and May 2014. This system utilizes a portable computer running Windows 7 to run the ultrasound application and a custom hardware designed engine for control of the acoustic array and processing of the return echoes. The engine is housed in a compartment that is inside the tablet.

The uSmart3200T system contains the same ultrasound engine as the predicate device Terason uSmart3200T ultrasound system for controlling the acoustic output of the transducer and processing the return echoes in real time. These data are then transferred to the tablet computer over a FireWire connection for further processing, and generation and display of the ultrasound image

The differences between the Terason uSmart3200T and the previous Terason uSmart3200T Ultrasound System (the predicate device) include the following:

- Five transducers have been added to the system along. The new Ophthalmic Indication for Use is associated with the 12L5A and 15L4 transducers. The Trans-esophageal (non-Cardiac and Cardiac) Indications for Use are also new. The software has been modified to control these transducers and ensure compliance to the standards controlling acoustic and thermal power.
- Added support for 9MC3, 8TE3, PDOF, 8L2, 8V3A transducers
    - Confirmed transducer id numbers and names
    - Confirmed transducer geometries and characteristic parameters
    - Confirmed 9MC3, 8TE3, PDOF, 8L2, 8V3A and ophthalmic-12L5A and 15L4 acoustic tables and added 8EC4A acoustic tables
    - Added 9MC3, 8TE3, PDOF, 8L2, 8V3A to the table of allowed transducers
    - Added imaging presets for 9MC3, 8TE3, PDOF, 8L2, 8V3A. Added presets for the new 15L4 and 12L5A ophthalmic mode. Added presets for the Trans-esophageal (non-Cardiac and Cardiac) modes.

7. Table of Similarities and Differences Compared to the Predicate Devices

Terason uSmart3200T System and Transducers Comparison and Discussion
New Transducers 9MC3, 8TE3, PDOF, 8L2, 8V3A, and for Ophthalmic Indication for Use 15L4 and 12L5A
Previously cleared transducers (12L5A, 5C2A, 4V2A, 8EC4A, 16HL7 and 15L4) (K140524)

Terason uSmart3200T Tablet Computer

	Subject Device Model **Terason uSmart3200T** **(This Submission)**	**Comparable Predicate Device** **Terason uSmart3200T** **K140524**	**Comparable Predicate Device** **Sonosite Maxx** **K071792**
Intended Use	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body
Indication for Use	Ophthalmic, Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal (non-Cardiac), Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel	Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Peripheral vessel	Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro), Laparoscopic, Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Convent.), Musculo-skel. (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel
Transducer Types	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Trans-esophageal PDOF	Linear Array Curved Array Phased Array Endocavity – curved array	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Trans-esophageal
Acoustic Output and FDA Limits	Display Features for High Outputs	Display Features for High Outputs	Display Features for High Outputs
Global Maximum Outputs/Worst Case Setting	$I_{SPTA.3}$: 652.9 mW/cm^2 (4V2A) TI Type: TIC (15L4) TI Value: 5.8 (15L4) MI: 1.78 (8EC4A) $I_{PA.3}$@MI Max: 827 W/cm^2 (15L4)	$I_{SPTA.3}$: 652.9 mW/cm^2 (4V2A) TI Type: TIC (15L4) TI Value: 5.8 (15L4) MI: 1.78 (8EC4A) $I_{PA.3}$@MI Max: 827 W/cm^2 (15L4)	N/A
Modes of Operation	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode Color Power Doppler	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode Color Power Doppler	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode Color Power Doppler

	Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler
PW Doppler	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF
Transducer Frequency	2.0 – 15.0 MHz	2.0 – 15.0 MHz	2.0 – 15.0 MHz (est.)
#Transmit Channels	128 Channels	128 Channels	128 Channels
# Receive Channels	128 Channels	128 Channels	128 Channels
Acoustic Output Measurement Standard	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-2004 NEMA UD 3-2004
DICOM	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM supported
Product Safety Certification	IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	IEC60601-1 IEC60601-1-2 IEC60601-1-4 IEC60601-2-37
EMC	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B
System Characteristics	**uSmart3200T:** tablet computer weighs 4.9 lbs (2.21 Kg) 11.5” backlit touch screen. Tablet dimensions (8.82”(H) x 12.64”(W) x 1.25”(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning Docking station (for charging) that uses a medical-grade power supply Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	**uSmart3200T:** tablet computer weighs 4.9 lbs (2.21 Kg) 11.5” backlit touch screen. Tablet dimensions (8.82”(H) x 12.64”(W) x 1.25”(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning Docking station (for charging) that uses a medical-grade power supply Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	**Sonosite Maxx:** Information available on the corporate web site: http://www.sonosite.com.

Five transducers have been added to the Terason uSmart3200T in this submission: 9MC3, 8TE3, PDOF, 8L2 and 8V3A. The new indications for use (IFU) that are included in this submission are for Ophthalmic use with the 12L5A and 15L4 transducer, and Trans-esophageal use with the 8TE3.

SUMMARY OF NEW AND ASSOCIATED PREDICATE TRANSDUCERS

New Subject Transducer	Comparable Predicate Transducer	Predicate Approvals and Systems
Terason 9MC3 micro-convex	Terason 8MC3 micro-convex	K112953 (Terason t3000)
Terason 8TE3 trans-esophageal	Philips S7-3t trans-esophageal	K132304 (Philips EPIQ) K070792 (Philips iE33)
Terason PDOF	Aloka UST-T109 PDOF	K110482 (Aloka ProSound C3)
Terason 8L2 linear	Terason 8L2 linear	K140773 (Terason uSmart3300)
Terason 8V3A phased	Terason 8V3A phased	K140773 (Terason uSmart3300)

TRANSDUCER PERFORMANCE SUMMARY

Transducer	Indications	Mode	Global maximum output	510(K) control number
12L5A	Ophthalmic, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Neonatal and Adult Cephalic, Musculo-sketetal (Conventional and Superficial), and Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 597(mW/cm$^{2)}$ TI = 3.3 MI = 1.8	K140524 changes to add ophthalmic use
4V2A	Fetal, Abdominal, Pediatric, Neonatal and Adult Cephalic, Cardiac (adult and pediatric)	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 603 (mW/cm$^{2)}$ TI = 5.6 MI = 1.5	K140524
5C2A	Fetal, Abdominal, Pediatric, Musculo-sketetal (Conventional and Superficial), Cardiac (adult and pediatric) and Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 660 (mW/cm$^{2)}$ TI = 4.7 MI = 0.7	K140524
8EC4A	Fetal, Trans-rectal, Trans-vaginal	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 633(mW/cm$^{2)}$ TI = 2.29 MI = 1.8	K140524
16HL7	Intra-Operative (abdominal, organs and vascular), Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular.	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 554(mW/cm$^{2)}$ TI = 1.22 MI = 1.6	K140524
15L4	Ophthalmic, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular.	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 563(mW/cm$^{2)}$ TI = 5.8 MI = 1.7	K140524 changes to add ophthalmic use
8L2	Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 598(mW/cm$^{2)}$ TI = 2.8 MI = 1.7	NEW
8V3A	Fetal, Abdominal, Pediatric, Cephalic, and Cardiac	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 560(mW/cm$^{2)}$ TI = 4.7 MI = 1.7	NEW
9MC3	fetal, pediatric, small organs, cephalic	B, M,	$I_{STPA.3}$ = 577(mW/cm$^{2)}$	NEW

	(neonatal and adult), cardiac and peripheral vessels	PWD, Color Doppler, CWD, Combined	TI = 2.8 MI = 1.3	
8TE3	Trans-esophageal (non-cardiac and cardiac)	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 245(mW/cm$^{2)}$ TI = 1.0 MI = 1.3	NEW
PDOF	Cardiac	CWD	$I_{STPA.3}$ = 506(mW/cm$^{2)}$ TI = 4.2 MI = 0.1	NEW

9MC3 Transducer

Key Features	**Subject Device Model** **Terason 9MC3 Transducer**	**Comparable Predicate Device** **Terason 8MC3 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K112953	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image fetal, pediatric, small organs, cephalic (neonatal and adult), cardiac and peripheral vessels.	The transducer is intended to be used with a conventional ultrasound system (Terason t3000) to image fetal, pediatric, small organs, cephalic (neonatal and adult), cardiac and peripheral vessels.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: **Same.** **Effectiveness**: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Micro Curved Array	Micro Curved Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 80 6.5 0.321mm X 6.0mm 30mm	 128 5.0 0.25mm X 8.0mm 40mm	**Different:** Element count, center frequency, element size and elevation focus. Acoustic characteristics have met safety guidelines of IEC60601-2-37. Safety and effectiveness unchanged from predicate.

Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K112953).	**Same:** The 9MC3 uses a same acoustic array materials as the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Silicone ABS	Silicone ABS	**Same**: Biocompatible.

Discussion:

The 9MC3 uses a same acoustic array materials as the predicate (8MC3) device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The transducer has been added to the uSmart3200T Ultrasound system.

The 9MC3 consists of same patient contact material as the predicate device. To ensure proper safety guidelines are met, biocompatibility tests were run on the patient contact materials.

Transducer 8TE3

Key Features	**Subject Device Model** **Terason(Oldelft) 8TE3 Transducer**	**Comparable Predicate Device** **Philips(Oldelft) S7-3t**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K132304 (EPIQ) K070792 (iE33)	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) for trans-esophageal (non-cardiac and cardiac) imaging.	The transducer is intended to be used with a conventional ultrasound system (Philips EPIQ) for trans-esophageal (non-cardiac and cardiac) imaging.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology	Piezoelectric elements	Piezoelectric elements	**Same**
Transducer Style	TE (Trans-esophageal)	TE (Trans-esophageal)	**Same.**
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…**	 64 5.0 MHz 0.16mm X 9.6mm 50mm	 64 5.0 MHz 0.16mm X 9.6mm 50mm	**Same.**

Elevation focus… **Array Rotation:** **Insertion length:** **Diameter:** **Bending capabilities:**	 180 degrees 41.0 mm (inflexible) 11.0 mm ≥ 120° upwards (clockwise rotation of knob) ≥ 90° backwards (counter-clockwise rotation of knob) ≥ 45° left ≥ 45° right	 180 degrees 41.0 mm (inflexible) 11.0 mm ≥ 120° upwards (clockwise rotation of knob) ≥ 90° backwards (counter-clockwise rotation of knob) ≥ 45° left ≥ 45° right	
Acoustic Output and Device Settings	The transducer performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filings (K132304, K070792).	**Same.**
Patient Contact Material	Silicone	Silicone	**Same.** The 8TE3 and the predicate S7-3t transducers are both manufactured by Oldelft and consist of identical patient contact materials.

Discussion:

There are no differences between this device and the predicate device used in this comparison. The transducer has been added to the uSmart3200T Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 8TE3 transducer is substantially equivalent to the predicate TE transducer with respect to safety and effectiveness.

PDOF Transducer

Key Features	**Subject Device Model** **Terason uSmart3200T PDOF Transducer**	**Comparable Predicate Device** **Aloka(Terason) ProSound C3 UST-T109 PDOF Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	KXXXXX	K110482	n/a

Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) for Cardiac continuous-wave Doppler (CWD) (adult and pediatric).	The transducer is intended to be used with a conventional ultrasound system (Aloka/Terason ProSound C3) for Cardiac continuous-wave Doppler (CWD) (adult and pediatric).	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Pencil Transducer	Pencil Transducer	
Acoustic Array Characteristics: **Element count…** **Center frequency** **Element size (diameter)…** **Elevation focus…**	 2 2.0MHz 13.8mm 55mm	 2 2.0MHz 13.8mm 55mm	**Same.**
Acoustic Array	The transducer CWD performance has been evaluated in an acoustic tank.	The transducer CWD performance has been evaluated in the previous 510(k) filing (K110482).	**Same.** As the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Epoxy Noryl	Epoxy Noryl	**Same.** The PDOF transducer consists of identical patient contact materials as the predicate device.

Discussion:

There are no differences between this device and the predicate device used in this comparison. The transducer has been added to the uSmart3200T Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason PDOF transducer is substantially equivalent to the predicate PDOF transducer with respect to safety and effectiveness.

8L2 Transducer

Key Features	**Subject Device Model** **Terason 8L2 Transducer**	**Comparable Predicate Device** **Terason 8L2 Transducer**	**Same or Different**

Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K140773	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3300) to image Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular.	**Same.**
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** **Same.** Regarding Safety: This array allows focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Linear Array	Linear Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 128 5.0 MHz 0.3mm X 6.0mm 40mm	 128 elements 5.0 MHz 0.3mm X 6.0mm 40mm	**Same.**
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K140773).	**Same.** As the predicate device and therefore has the same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	SIM R100	SIM R100	**Same.**

The uSmart3200T uses a same 8L2 transducer as the predicate uSmart3300 device and therefore has identical acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The 8L2 transducer used with the uSmart3200T consists of the same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 8L2 transducer meets safety and effectiveness guidelines.

8V3A Transducer

Key Features	**Subject Device Model** **Terason 8V3A Transducer**	**Comparable Predicate Device** **Terason 8V3A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K140773	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Cephalic, and Cardiac.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3300) to image Fetal, Abdominal, Pediatric, Cephalic, and Cardiac.	**Same.**
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: This array allows focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Phased Array	Phased Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 96 4.7 MHz 0.16mm X 8mm 49mm	 96 4.7 MHz 0.16mm X 8mm 49mm	**Same.**
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K140773).	**Same.** As the predicate device and therefore has identical acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Silicone Valox	Silicone Valox	**Same.**

The uSmart3200T uses a same 8V3A transducer as the predicate uSmart3300 device and therefore has identical acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The 8V3A transducer used with the uSmart3200T consists of the same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 8V3A transducer meets safety and effectiveness guidelines.

15L4 Transducer

Key Features	**Subject Device Model** **Terason 15L4 Transducer**	**Comparable Predicate Device** **Sonosite Edge L25x/13-6 Transducer**	**Same or Different**
510(k) Number	K1XXXXX	K082098	n/a
Classification	ITX	ITX	**Same**
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image ophthalmic, abdomen, small parts, musculo-skel, peripheral vascular regions. Ophthalmic is the new IFU.	The transducer is intended to be used with a conventional ultrasound system (Sonosite Edge) to image ophthalmic, abdomen, pediatric, small parts, musculo-skel and peripheral vascular regions.	**Different:** The proposed transducer and the predicate transducer have the claim of imaging similar regions in the human body. Ophthalmic is the new Indication for Use.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same:** Safety requirements of IEC60601 are equally met. **Effectiveness:** Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Linear Array	Linear Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 128 elements 7.5 MHz 0.3mm X 4.0mm 20mm	 128 elements 9.5 MHz (est) 0.195mm X 3.0mm (est) 18mm (est)	**Same:** element count. Acoustic characteristics have met safety guidelines of IEC60601-2-37.
Acoustic Output and Device Settings	The transducer performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the 510(k) filing (K082098).	**Different;** acoustic output safety guidelines. Safety is not compromised. Effectiveness equal.

Patient Contact Material	Silicone ABS	Silicone ABS	**Same.** The 15L4 transducer consists of same patient contact materials as the predicate device. The safety of each device with respect to biocompatibility is equivalent.

Discussion:
The 15L4 uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines for ophthalmic use are met, acoustic testing was performed per the IEC60601-2-37 standard. The 15L4 transducer consists of same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 15L4 transducer is substantially equivalent to the Sonosite L25x transducer (K082098) with respect to safety and effectiveness. Based on test results, the 15L4 transducer can be safely used for ophthalmological use.

12L5A Transducer

Key Features	**Subject Device Model** **Terason 12L5A Transducer**	**Comparable Predicate Device** **Sonosite Edge L25x/13-6 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	KXXXXX	K082098	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image ophthalmic, fetal, abdominal, pediatric, small organ, cephalic, musculo-skel, cardiac and peripheral vessel. Ophthalmic is the new IFU.	The transducer is intended to be used with a conventional ultrasound system (Sonosite Edge) to image ophthalmic, abdomen, pediatric, small parts, musculo-skel and peripheral vascular regions.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Linear Array	Linear Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…**	 128 7.5MHz 0.3mm X 4.0mm 19mm	 128 9.5MHz (est) 0.195mm X 3.0mm (est) 18mm (est)	**Same in elevation** Safety and effectiveness unchanged from predicate

Elevation focus…			
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K082098).	**Same.** As the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Silicone ABS	Silicone ABS	**Same.** The 12L5A transducer consists of same patient contact materials as the predicate device.

Discussion:
The 12L5A uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines for ophthalmic use are met, acoustic testing was performed per the IEC60601-2-37 standard. The 12L5A transducer consists of same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 12L5A transducer is substantially equivalent to the Sonosite L25x transducer (K082098) with respect to safety and effectiveness. Based on test results, the 12L5A transducer can be safely used for ophthalmological use.

Previously filed transducers:

The following transducers are identical to those previously cleared under FDA 510(k) K140524, March 21, 2014 for the Terason uSmart3200T:

- 4V2
- 5C2A
- 8EC4A
- 12L5A (not including Ophthalmic use)
- 15L4 (not include Ophthalmic use)
- 16HL7.

Conclusion:

The intended uses and features are consistent with the traditional clinical practices and FDA guidance for clearance of Diagnostic ultrasound systems and transducers. The uSmart3200T and predicate devices both conform to applicable electric safety medical device standards with compliance verified through independent evaluation. The uSmart3200T and predicate devices both meet FDA requirements for track 3 devices, indications for use, biocompatibility similarities, and are manufactured using FDA GMPs and ISO-13485 quality systems. Teratech Corporation believes that the uSmart3200T ultrasound system is substantially equivalent with regards to safety and effectiveness to the predicate devices.

8. Summary of Bench Tests and Non-Clinical Tests

The Terason uSmart3200T system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
  - Intertek Project: 100825075BOX-003
- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
  - Oldelft EMC Technical Report 2011-002
  - EMC Emissions Evaluation of Terason uSmart3200T with 3 port MUX, Intertek 100933162BOX-017
  - EMC Emissions Evaluation of Terason uSmart3200T with 8L2, 8V3A, PDOF, 9MC3 Transducers, Intertek 101753691BOX-001
  - EMC Emissions Evaluation of uSmart3200T Cart with 8TE3 Transducer, Intertek 101885790BOX-002

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
  - 4V2A Transducer
  - 5C2A Transducer
  - 8EC4A Transducer
  - 16HL7 Transducer
  - 8TE3 Transducer
  - 8L2Transducer
  - 8V3ATransducer
  - 9MC3 Transducer
  - 12L5A Transducer
  - 15L4 Transducer
  - PDOF Transducer

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
  - Biocompatibility reports for the new transducers
- AAMI TIR No. 12:210, Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.

The ultrasound system acoustic output was test in accordance with the following:

- IEC 61157, Ed. 2 2007-2008, Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3
- NEMA UD 3, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2.

The ultrasound system B-Mode Accuracy, Doppler Accuracy and Doppler Sensitivity for each Terason transducer have been evaluated according to the following:

- American Institute of Ultrasound in Medicine (AIUM) Quality Assurance Manual for Gray-Scale Ultrasound Scanners
- AIUM Methods for Measuring Performance of Pulse-Echo Ultrasound Imaging Equipment, Part II: Digital Methods
- AIUM Performance Criteria and Measurements for Doppler Ultrasound Devices.

The Terason uSmart3200T Software has undergone Quality Assurance testing consistent with IEC 62304, Software Life Cycle Process, and IEC 62366, Application for Usability.

9. Summary of Conclusions

The predicate system (uSmart3200T, K140524) and associated predicate transducers (Terason 8MC3, K112953; Philips S7-3t, K132304 and K070792; Aloka UST-T109 PDOF, K110482; Terason 8L2 and 8V3A, K140773) are legally marketed. The new system and associated transducers have the same intended use as the predicate system and devices. The Terason uSmart3200T and associated transducers represent a new implementation of familiar technology and therefore possess new technological characteristics that are validated in this filing. The performance data used to validate the Terason uSmart3200T and 9MC3, 8TE3, PDOF, 8L2 and 8V3A transducers includes the following:

- Acoustic output testing

- B-Mode accuracy, and Doppler accuracy and sensitivity
- General requirements for safety testing
- Electromagnetic compatibility testing
- Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment testing
- Biocompatibility testing of patient contact materials
- Burn-in testing
- Software performance and regression testing.